IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9073

Bartle, J. May 22, 2013

Carol LaFleur ("Ms. LaFleur" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Kevin R. LaFleur, Ms. LaFleur's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2007, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Steven J. Schang, Jr., M.D., F.A.C.P., F.A.C.C. Based on an echocardiogram dated March 20, 2007, Dr. Schang attested in Part II of Ms. LaFleur's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension,

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

and a reduced ejection fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $560,748.[5]

In the report of claimant's March 20, 2007 echocardiogram, the reviewing cardiologist, Kim J. Coffman, M.D., F.A.C.C., found moderate mitral regurgitation of 35%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2007, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for Dr. Schang's finding that claimant had moderate mitral regurgitation because the March 20, 2007 echocardiogram demonstrated only mild mitral

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4. Dr. Schang also attested that claimant suffered from moderate aortic regurgitation and pulmonary hypertension secondary to severe aortic regurgitation. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue in connection with this Green Form is claimant's level of mitral regurgitation.

regurgitation. Dr. Gradus-Pizlo explained, "Non-turbulent flow area was measured."

Based on Dr. Gradus-Pizlo's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. LaFleur's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted an affidavit from her attesting physician and a letter from Paul Tamburro, M.D., F.A.C.C. In his affidavit, Dr. Schang stated:

> I disagree with the auditing cardiologist's conclusion with respect to Mrs. LaFluer's degree of mitral regurgitation. I direct the auditing cardiologist to frame 9:19:15 of the echocardiogram tape/dvd, which clearly evidencing [sic] a regurgitant jet area of 5.5 cm^2 measured in the apical four-chamber view and a left atrial area of 18.1 cm^2. The auditing cardiologist's suggestion that "non turbulent flow area was measured" is wrong. The measurements were clearly taken from turbulent jet which appears as a mosaic blue turbulent flow in frame 9:19:15. Moderate mitral regurgitation can also be seen at frame 9:15:37, also captured and appearing at the end of the echocardiogram videotape/dvd. While the sonographer's measurement on frame 9:15:37 may have been a slight overestimation of the [left atrium], it still measures 6.2 cm^2 with regurgitant jet area of 18 cm^2 - a regurgitant jet area of greater than 20% of

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> the left atrial area. Thus, it is clear that Mrs. LaFluer has moderate mitral regurgitation.

(Citations omitted.) Dr. Schang also included still-frame images he argued supported these statements. Dr. Tamburro observed:

> In my opinion Ms. Lafleur has moderate ... mitral regurgitation. Specifically regarding mitral regurgitation, I agree with the auditing cardiologist that the regurgitant jet to left area ratio may be overstated in the study but still appears to be greater than 20%, therefore it is moderate mitral insufficiency.

In addition, claimant argued that she should prevail because three board-certified cardiologists, one of whom participated in the Trust's Screening Program,[7] concluded that her March 22, 2007 echocardiogram revealed moderate mitral regurgitation. Claimant contended that the standard is not whether the auditing cardiologist agrees with claimant's attesting physician, but rather if there is a reasonable medical basis for the attesting physician's finding. Claimant further argued that the doctrine of inter-reader variability may account for the differences in the opinions of the attesting physician and the auditing cardiologist. Finally, claimant asserted that the auditing cardiologist's conclusion should not be accepted because the auditing cardiologist did not "provide any substantive analysis or objective measurements."

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7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

Although not required to do so, the Trust forwarded this claim to the auditing cardiologist for a second review. Dr. Gradus-Pizlo submitted a declaration in which she confirmed her previous conclusion that there was no reasonable medical basis for Dr. Schang's finding that claimant had moderate mitral regurgitation. In her declaration, Dr. Gradus-Pizlo stated, in relevant part:

> 8. In accordance with the Trust's request, I again reviewed the entirety of Claimant's March 20, 2007 echocardiogram tape, as well as Claimant's Contest Materials.
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> 9. Based on my review, I again confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant's March 2007 echocardiogram demonstrates moderate mitral regurgitation and pulmonary hypertension secondary to moderate or greater mitral regurgitation.
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> 10. In addition, I find that Claimant's Contest Materials fail to establish a reasonable medical basis for the Attesting Physician's representation that Claimant's March 2007 echocardiogram demonstrates moderate mitral regurgitation.
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> 11. At Contest, I reviewed the entirety of Claimant's March 20, 2007 echocardiogram, including those points specifically identified by Dr. Schang in his Affidavit. This echocardiogram study does not contain continuous study material; rather, the study is comprised of a series of still frames and moving clips of short duration. The majority of the images seen are in fact still frames. Observing the March 2007 echocardiogram in its entirety I affirm my finding at audit that the

> echocardiogram does not demonstrate any sustained jet of moderate mitral regurgitation; only sustained mild mitral regurgitation is seen.
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> 12. I examined the March 2007 echocardiogram at 9:19:15, which Dr. Schang indicates shows moderate mitral regurgitation with an RJA/LAA ratio of 5.5cm/18.1cm. While a measurement of 18.1cm is applied on screen, this frame does not include color Doppler making it impossible to determine what, if any, flow is measured here.
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> 13. I also examined the March 2007 echocardiogram at frame 9:15:37, identified by Dr. Schang as capturing a regurgitant jet greater than 20% of the LAA. This frame is the last in a series of still frames from 9:15:23 through 9:15:37. The frame 9:15:37 is not representative of mitral regurgitation present in this study. In addition, the frame at 9:15:37 does not demonstrate mitral regurgitation. The EKG seen at the bottom of the frame clearly demonstrates that this frame occurs in diastole; mitral regurgitation is found in systole.
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> 14. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that Claimant's March 2007 echocardiogram demonstrates moderate mitral regurgitation and pulmonary hypertension secondary to moderate or greater mitral regurgitation.

The Trust then issued a final post-audit determination again denying Ms. LaFleur's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why Ms. LaFleur's claim should be paid. On August 21, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7925 (Aug. 21, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, which consisted solely of the submission of claimant's contest materials. By letter dated November 21, 2008, the Trust advised the Special Master that it did not intend to submit a reply.

In October, 2009, claimant submitted a second completed Part II of a Green Form to the Trust signed by her attesting physician, Dr. Schang. Based on an echocardiogram dated September 23, 2008, Dr. Schang attested that Ms. LaFleur suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[8] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $554,232.[9]

In the report of claimant's September 23, 2008 echocardiogram, Dr. Schang stated that claimant had "[m]oderate

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8. Dr. Schang also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

9. As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue in connection with this Green Form is claimant's level of mitral regurgitation. See Settlement Agreement § IV.B.2.c.(2)(b).

[m]itral [i]nsufficiency, RJA/LAA=35%." As noted, moderate or greater mitral regurgitation is present where the RJA in any apical view, is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22.

In November, 2009, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Schang's finding that claimant had moderate mitral regurgitation because the September 23, 2008 echocardiogram demonstrated only mild mitral regurgitation. Dr. Irani explained, "Overtracing of jet to include noncolor encoded areas and low velocity non regurgitant flow areas."

Based on Dr. Irani's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. LaFleur's second claim. Pursuant to the Audit Rules, claimant also contested this adverse determination.[10] In contest, claimant submitted an affidavit from her attesting physician, Dr. Schang, wherein he reaffirmed his finding of moderate mitral regurgitation. Dr. Schang explained:

> I disagree with the Auditing Cardiologist's conclusion with respect to Ms. LaFluer's degree of mitral regurgitation. I direct a reviewer to a point in the DVD copy 4 minutes 47 seconds from the beginning of the recorded copy of the echocardiogram frozen just after frame 29:59:17 which clearly demonstrates a

10. There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim as well.

> regurgitant jet area/left atrial area of more than 30% measured in the apical four chamber view. Also, moderate mitral regurgitation can be clearly seen and measured in the apical two chamber view at frame 10:06:23 with an RJA/LAA of greater than 35%. The Auditing Cardiologist's opinion that "overtracing of jet to include non color coded areas and low flow velocity non regurgitant flow areas" is wrong and thus his opinion that there was no reasonable medical basis for the answer given on the Claim Form was in error. The measurements were clearly taken from the same frame of the study in question and included the color as described by Singh in his original article as quoted by the AHP Settlement Trust as the standard by which the echocardiogram and cardiac Doppler studies in question are to be interpreted.

In addition, claimant argued that the doctrine of inter-reader variability may account for the difference in the respective opinions of Dr. Schang and Dr. Irani. Finally, claimant asserted that the auditing cardiologist's conclusion should not be accepted because the auditing cardiologist did not follow the Settlement Agreement or "provide any substantive analysis or objective measurements."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Irani submitted a declaration in which he confirmed his conclusion that there was no reasonable medical basis for Dr. Schang's finding that claimant had moderate mitral regurgitation. In his declaration, Dr. Irani stated, in relevant part:

> 8. In accordance with the Trust's request, I reviewed Claimant's file and Contest

> Materials, as well as Claimant's September 23, 2008 echocardiogram tape.
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> 9. Based on my review, I confirm my audit findings, that there is no reasonable medical basis for the Attesting Physician's representations that Claimant has moderate mitral regurgitation ....
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> 10. With regard to mitral regurgitation, I find that Claimant's Contest Materials do not establish a reasonable medical basis for the Attesting Physician's representation of moderate mitral regurgitation. At audit, I found overtracing of the mitral regurgitant jet, which included non-color encoded areas and low velocity, non regurgitant flow. At Contest, I reviewed the entirety of the September 23, 2008 study, including the images identified by Dr. Schang in his affidavit, and again observed overtracing of the mitral regurgitant jet. I examined the study at 29:59:17, where Dr. Schang states he observed moderate mitral regurgitation with an RJA/LAA ratio of over 30%. I digitized the study and measured an RJA of 2.85 cm^2. A printout of my measurements is attached to this Declaration as Exhibit B. The LAA at 29:59:17 was anteriorly titled, foreshortening the [left atrium] and making proper measurement impossible. Accordingly, I also traced the LAA at 29:57:45 and measured an LAA of 19.41 cm^2, for a ratio of 14.6%.... Even taking the largest possible LAA, mitral regurgitation is only mild.

The Trust then issued a final post-audit determination again denying Ms. LaFleur's second claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

The Trust then applied to the court for issuance of an Order to show cause why Ms. LaFleur's second claim should be paid. On June 9, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8487 (June 9, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, which consisted solely of the submission of claimant's contest materials. By letter dated August 17, 2010, the Trust advised the Special Master that it did not intend to submit a reply.

The issue presented for resolution of these claims is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation based on either her March 20, 2007 or September 23, 2008 echocardiograms. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Forms that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See id. Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Records and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The Technical Advisor, Dr. Vigilante, reviewed claimant's March 20, 2007 and September 23, 2008 echocardiograms and concluded that there is no reasonable medical basis for finding moderate mitral regurgitation because each echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Vigilante stated:

> I reviewed the third echocardiographic tape. This was a copy of the study performed on March 20, 2007.... All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. There was significantly increased color gain during the color Doppler evaluation. There was color artifact noted throughout the

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

study. However, the Nyquist limit was appropriately set at 69 cm per second at a depth of 16 cm in the parasternal long-axis view and 69 cm per second at a depth of 18 cm in the apical views. Inappropriate measurements were taken. In addition, there were very few cardiac cycles of the mitral regurgitant jet in the apical views. Many still frames were present on this study.

.... Visually, a mild and laterally directed mitral regurgitant jet was noted traveling into the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best identified. I was able to measure the RJA in the mid portion of systole. The largest representative RJA in the apical four chamber view was 3.7 cm2. The LAA in the apical four chamber view was 20.1 cm2. Therefore, the largest representative RJA/LAA ratio was 18% qualifying for mild mitral regurgitation. This ratio did not reach 20%. The RJA was less than 3.0 cm2 in the apical two chamber view. The sonographer calculated an RJA of 6.42 cm2. However, this was a still frame and not representative of mitral regurgitation. In addition, the time frames of 9:15:37 and 9:19:15 documented by the Attesting Physician were reviewed. These images were not reflective of mitral regurgitation seen in real time.

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I reviewed the fourth echocardiographic tape. This was a copy of the September 23, 2008 echocardiogram.... All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. There was increased color gain during color Doppler evaluation with color artifact noted within the myocardium and outside of the heart. In addition, there was abnormal persistence with stuttering of color images in the parasternal and apical views. The Nyquist limit was borderline low at 59 cm per second at a depth of 16 cm in the parasternal

> long-axis view and 53 cm per second at a depth of 18 cm in the apical views.
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> .... Visually, only mild mitral regurgitation was suggested with a small laterally directed jet noted to go posterolaterally in the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was identified. I measured the RJA and LAA with electronic calipers. The largest representative RJA in the apical four chamber view was 2.5 cm[2] per second. The LAA in the apical four chamber view was 19.2 cm2. Therefore, the largest RJA/LAA ratio was 13% qualifying for mild mitral regurgitation. This ratio never came close to approaching 20%. The RJA was less than 2.0 cm2 in the apical two chamber view. The time frames of 9:59:17 and 10:06:23 documented by the Attesting Physician were scrutinized on this study. Only mild mitral regurgitation was present at these time frames.

After reviewing the entire Show Cause Record, we find claimant's arguments without merit. As an initial matter, neither the supplemental affidavits of Dr. Schang nor the letter from Dr. Tamburro provides a reasonable medical basis for Dr. Schang's representations of moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified

Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). In addition, we have stated that "although still frames are necessary to determine a claimant's level of mitral regurgitation, they are not sufficient alone." PTO No. 6897 at 7 (Jan. 26, 2007). "Only after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved." Id. (quoting PTO No. 2640 at 9).

Here, Dr. Gradus-Pizlo determined that claimant's March 20, 2007 echocardiogram demonstrated only mild mitral regurgitation because the measurements on the echocardiogram tape included "[n]on-turbulent flow area."[12] Although Dr. Schang disputed that his measurements included "[n]on-turbulent flow area" and included still-frame images purportedly demonstrating moderate mitral regurgitation, claimant's own expert,

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12. For this reason as well, we reject claimant's argument that Dr. Gradus-Pizlo did not provide a substantive analysis or that she simply disagreed with Dr. Schang.

Dr. Tamburro, agreed that the RJA evidenced on the echocardiogram was overstated. In addition, Dr. Vigilante concluded that claimant's March 20, 2007 echocardiogram demonstrated only mild mitral regurgitation, explaining that the RJA measured on the echocardiogram tape "was a still frame and not representative of mitral regurgitation."[13] Dr. Vigilante also reviewed the still-frame images included by Dr. Schang and concluded that they "were not reflective of mitral regurgitation seen in real time."

With respect to claimant's September 23, 2008 echocardiogram, Dr. Irani determined that claimant had only mild mitral regurgitation. Dr. Irani observed, "Overtracing of jet to include noncolor encoded areas and low velocity non regurgitant flow areas."[14] Dr. Schang also disputed Dr. Irani's conclusion, identifying two frames he submitted demonstrated an RJA/LAA ratio of more than 30%. Dr. Vigilante, however, reviewed claimant's September 23, 2008 and concluded that it demonstrated only mild mitral regurgitation. He also reviewed the time frames submitted by Dr. Schang and determined that "[o]nly mild mitral regurgitation was present at these time frames." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnoses and Green Form answers.[15]

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13. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

14. For this reason as well, we reject claimant's argument that Dr. Irani did not provide a substantive analysis.

15. Thus, we reject claimant's argument that there is a (continued...)

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representations that she had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinions cannot be medically reasonable where, after audit, it is determined that claimant did not have the requisite level of regurgitation because low velocity flow improperly was included in the determination of the level of claimant's mitral regurgitation. Adopting claimant's position would allow claimants always to avoid the findings of the auditing cardiologist by simply asserting, as claimant does here, that there is merely a "difference of opinion." This result would render meaningless that provision of the Settlement Agreement that requires at least moderate mitral regurgitation to recover Level II Matrix Benefits.[16]

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15. (...continued)
reasonable medical basis for her claim simply because one of her physicians participated in the Trust's Screening Program.

16. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statements, with respect to each echocardiogram, that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study when making quantitative measurements [of the mitral regurgitant jet] even taking into account inter-reader variability."

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation based on either her March 20, 2007 or her September 23, 2008 echocardiograms. Therefore, we will affirm the Trust's denials of Ms. LaFleur's claims for Matrix Benefits and the related derivative claims submitted by her spouse.